

## **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **I. Status of Claims**

1. Claims 1, 3-5, 7-12, 18, 20-23, and 25-36 are currently pending in the application.
2. Claim 1 has been amended. The amendments have been made without the introduction of new matter. Support for the amendment to claim 1 is found in the specification at Example 2 and Table 1, in the published application at paragraphs [0041-0050].
3. New claims 33-34 have been added without the introduction of new matter. Support for claims 33-34 are found in the published application at paragraph [0027].
4. New claim 35 has been added without the introduction of new matter. Support for claim 35 is found in the published application at paragraph [0050].
5. New claim 36 has been added without the introduction of new matter. Support for claim 36 is found in the published application at paragraph [0043].
6. Claims 18, 20-23 and 25-28 have been cancelled without waiver or prejudice.
7. Claims 5 and 8 have been amended without the introduction of new matter to change their dependency to claim 32.
8. Applicants reserve the right to pursue the subject matter of any cancelled claims in one or more continuing applications.
9. Following the above amendments claims 1, 3-5, 7-12 and 29-35 remain pending in the application.

### **II. Claim Rejections under 35 U.S.C. §103(a)**

10. Claims 1, 3-5, 7-12 and 29-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Athwal et al.*, (WO01/94585) (hereafter the '585 publication) in view of *Relton*, (WO97/45140) (hereafter the '140 publication) as evidenced by U.S Patent No. 6,171,586 (hereafter the '586 patent). Applicants respectfully traverse this rejection.
11. The Examined has argued that the stabilizing antibody formulation, as noted at page 4 line 26 of the '140 publication extends bispecific molecules and presumably to Fab fragments. Further the Examiner points to the teaching of the '586 patent that the bispecific antibodies include cross-linked or heteroconjugated antibodies such as

biotin and avidin and thionitrobenzoate, as noted at col.16, lines 36-63. In view of these combined teachings the Examiner has argued that one of ordinary skill in the art would stabilize a modified antibody formulation as taught in the '585 publication with a formulation comprising a buffer comprising acetate at pH 4.0-6.0 as taught by the '140 publication.

12. It is respectfully submitted that a *prima facie* rejection under 35 U.S.C. §103(a) has not been properly established by the combined teachings of the '585 and '140 publications as evidenced by the '586 patent. Applicants note that the teachings of the combined references provide no suggestion that the disclosed buffer system of the '140 publication would be suitable to an antibody described in the '585 publication and maintain the stability of the antibody formulation for at least twelve weeks at 25° C. and to 40° C. as shown in Example 2 of the present application. Consequently, one of skill in the art would not have been motivated to combine the teachings of the two publications believing to have a reasonable expectation of sources in producing Applicants' temperature stable antibody-nonproteinaceous polymer formulation as noted in claim 1 and in claim 36.

13. Applicants respectfully request the Examiner to reconsider the rejection of claims 1, 3-5, 7-12 and 29-32 and withdraw the rejection under 35 U.S.C. §103 (a).

### **III Claim rejections under 35 USC § 112**

14. Claims 5 and 8 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter to which Applicants regard as their invention. Applicants respectfully traverse this rejection.

15. Claims 5 and 8 have been amended to recite their dependency on claim 32 and thus moot this rejection.

16. Applicants respectfully request that the Examiner reconsider the rejection of claims 5 and 8 and withdraw the rejection under 35 USC §112, second paragraph.

17. Claims 1, 3-4, 7, 9-12, 29-31 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the cleared invention. Applicants respectfully traverse this rejection.

18. The examiner has argued the paragraph [0026] of the published application does not disclose that the modified antibody can be made without a linker comprising a succinimide moiety. Applicants disagree as paragraph [0026] of the published application recite broadly the covalent attachment of the modified antibody to the nonproteinaceous polymer. Applicants further point to paragraph [0025] of the published application as reciting various modifying groups that may be utilized to covalently attach the modified antibody to the nonproteinaceous polymer.

19. Applicants request reconsideration of claims 1, 3-4, 7, 9-12, 29-31 and the withdrawal of the rejection under 35 USC §112, first paragraph.

**IV. Provisional claim rejections under the judicially created doctrine of double patenting**

20. Claims 1, 3-5, 7-12 and 29-32 were provisionally rejected under the judicially created doctrine of double patenting over claims 39-50 and 54-57 of copending Application No. 10/634, 199.

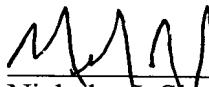
21. As this is a provisional double patenting rejection, Applicants respectfully request that this rejection be deferred until such time as the claims of the noted application have been patented.

**IV. Conclusion**

22. Applicants respectfully submit that all the grounds for rejection of the pending claims have now been overcome and that all the claims are now in condition for allowance.

23. In the event that the Examiner wishes to discuss any aspect of this response for purposes of advancing the prosecution, please contact the undersigned attorney at the telephone number provided below.

Respectfully submitted,

  
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